UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION	**MDL No. 16-2738 (MAS)(RLS)**
THIS DOCUMENT RELATES TO ALL CASES	

THE PLAINTIFFS' STEERING COMMITTEE'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO EXCLUDE THE OPINIONS OF DR. JENNIFER PERMUTH

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The PSC respectfully submits this memorandum of law in support of its motion to exclude portions of the testimony of the Johnson & Johnson Defendants'[1] ("J&J") expert witness Jennifer Permuth, PhD., MS, pursuant to Federal Rule of Evidence 104 (a), 702, 703 and 403.

I. INTRODUCTION AND SUMMARY

The general and specific causation opinions of Dr. Permuth are based on speculation and flawed methodology concerning a biologically plausible mechanism and should be excluded.[2] *First*, as to specific causation, Dr. Permuth speculates that imaginary gene mutations, that none of the Plaintiffs have and/or are not related to the development of ovarian cancer, are to blame for Plaintiffs' ovarian cancers. These opinions are based on pure speculation and thus, must be excluded.

Second, Dr. Permuth's opinions concerning biological plausibility are based on flawed methodology because she fails to consider the actual constituents in talcum powder. Although Plaintiffs allege asbestos is in talcum powder, Dr. Permuth pretends it does not exist. She deliberately ignores the evidence, literature and science on asbestos, and at best, cherry picks studies to support her conjecture

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[1] The Johnson & Johnson Defendants include Johnson & Johnson, Johnson & Johnson Consumer Inc., n/k/a/ Johnson & Johnson Consumer Companies, Inc., LTL Management LLC, Johnson & Johnson Holdco (NA), Inc., Kenvue, Inc., and Janssen Pharmaceuticals, Inc.

[2] *Calhoun v. Yamaha Motor Corp*., U.S.A., 350 F.3d 316, 321 (3d Cir. 2003) ("…the testimony must be reliable….'the expert's opinion must be based on the methods and procedures of science rather than on subjective belief or unsupported speculation…") (citations omitted). *See also Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 405 (3d Cir. 2003).

disguised as legitimate conclusions.

Finally, Dr. Permuth's opinions on biological plausibility are based on an incorrect standard, requiring perfected proof of mechanism rather than simply a plausible mechanism as the science and law require.

II. LEGAL STANDARD

The PSC incorporates the legal standard set forth in The Plaintiffs' Steering Committee's Brief Regarding the Rule 702 Standard ("Rule 702 Standard Brief") and supplements it as set forth herein.

III. OVERVIEW OF J&J'S EXPERT, DR. JENNIFER PERMUTH

Dr. Permuth is a molecular epidemiologist.[3] Her opinions, in pertinent part, may be summarized as follows: (1) there are known factors that increase or decrease the risk of the development of ovarian cancer;[4] (2) the epidemiological data does not demonstrate a causal relationship between talc and ovarian cancer;[5] (3) the literature fails to demonstrate a coherent and biologically plausible mechanism;[6] and (4) there is a lack of evidence of talc carcinogenicity.[7] Dr. Permuth does not opine on the individual ingredients in talcum powder, including whether asbestos, fibrous talc,

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3 Expert Report of Jennifer B. Permuth, PhD., MS (May 28, 2024) ("Permuth Report") at 4, attached hereto as **Exhibit 1**.

4 Permuth Report at 148, Exhibit 1.

5 *Id.*

6 *Id.*

7 *Id.*

platy talc, heavy metals, or fragrances can cause or increase the risk of ovarian cancer.

Dr. Permuth also provides specific causation opinions related to four bellwether plaintiffs: Linda Bondurant, Hilary Converse, Carter Judkins and Tamara Newsome. Because she concludes that talcum powder does not contribute to ovarian cancer, she does not find that it is a cause of Plaintiffs' ovarian cancers.

Instead, Dr. Permuth opines that Ms. Bondurant's ovarian cancer is linked to her SDHA germline mutation, her history of endometriosis, and/or a yet-to-be-identified mutation causing hereditary breast and ovarian cancer.[8] As to Ms. Converse, Dr. Permuth points to genetic variants of uncertain significance (VUSs), although she admitted that the VUSs in question have not been classified as pathogenic or deleterious.[9] As to Ms. Judkins, Dr. Permuth again points to a genetic VUS, while admitting that the clinical significance of this mutation as a contributing cause is unknown and only a possibility.[10] Similarly, as to Ms. Newsome, Dr. Permuth diverts attention to a VUS in Ms. Newsome's genetic testing, while again admitting there are insufficient data to determine if said variant causes increased cancer risk.[11]

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8 Permuth Report at 145, Exhibit 1.

9 Permuth Report at 146, Exhibit 1; Deposition of Jennifer Permuth (June 13, 2024) ("Permuth Dep.") at 325:22-326:14, attached hereto as **Exhibit 2**.

10 Permuth Report at 147, Exhibit 1; Permuth Dep. at 330:2-9, Exhibit 2.

11 Permuth Report at 147, Exhibit 1.

IV. DR. PERMUTH PROVIDES UNSUPPORTED OPINIONS ON IMAGINARY GENETIC MUTATIONS

Dr. Permuth theorizes that unknown genetic mutations, which science has not identified as being associated with ovarian cancer, may have caused Plaintiffs' ovarian cancers. These opinions are speculative and must be excluded.

It is not disputed in this litigation that there are known genetic mutations, most notably BRCA1 and BRCA2, that can increase a woman's risk of developing epithelial ovarian cancer.[12] Dr. Permuth makes no claim that Plaintiffs have these known mutations. Yet, she speculates that in the future, new mutations will be identified and associated with ovarian cancer that could be the cause of Plaintiffs' cancers.

Regarding Ms. Bondurant:

- Taken together, the possibility remains that Ms. Bondurant's OvCa is linked to her SDHA germline mutation, her history of endometriosis, and/or a yet-to-be-identified mutation causing HBOC.[13]

- Q. Can you say to a reasonable degree of medical certainty that an unknown genetic mutation is a cause of Ms. Bondurant's ovarian cancer?
  [Objection]
  A. I guess all I can do is restate the last sentence of my paragraph on Ms. Bondurant: The possibility remains that her ovarian cancer is linked to her SDHA germline mutation, her history of endometriosis, and/or a yet-to-be-identified mutation causing hereditary breast and ovarian cancer.

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12 *See* Third Amended Expert Report of Judith Wolf, MD at 3, attached hereto as **Exhibit 3**.

13 Permuth Report at 145, Exhibit 1 ("Hereditary Breast Ovarian Cancer Syndrome").

Q. So your opinion is it's a possibility?
A. Yes.[14]

Regarding Ms. Converse:

- Q. Do you have any evidence that the VUS in ATM and TGFBR2 are related to ovarian cancer, pathogenic for ovarian cancer?
  A. It's unclear, as I said in my report, but certainly variants in these genes have been seen in families with ovarian cancer, particularly of the clear cell type like she had, as well as breast cancer.
  Q. And what's your reference for that?
  A. I believe I had a citation in here that I'm not seeing right now, so I would have to look into that.
  Q. Yeah, I did not see a citation.
  A. Yeah, I don't know if it was accidentally deleted.
  Q. Does ClinVar consider either of those a deleterious VUS?
  A. Not at this point. Science evolves.[15]

- Both of these variants were later identified in her mother who had early-onset breast cancer, but to date, ClinVar suggests the pathogenicity of these variants is unclear.[16]

Regarding Ms. Judkins:

- Q. Is it your opinion that the PTEN variant is, to a reasonable degree of medical certainty, a contributing cause of her ovarian cancer?
  A. It may have been.
  Q. To a reasonable degree of medical certainty is it a contributing cause?
  A. As I said, it may have been. It's a possibility.[17]

- The c.-1283G>A variant detected in the blood of Ms. Judkins is located in the 5' untranslated region of PTEN in the promoter region. Although its clinical significance is unknown at this time according to ClinVar, variants in this region have been shown to be

[14] Permuth Dep. at 321:21-322:9, Exhibit 2.
[15] Permuth Dep. at 325:22-326:14, Exhibit 2.
[16] Permuth Report at 146, Exhibit 1.
[17] Permuth Dep. at 330:2-9, Exhibit 2.

deleterious and to produce reduced PTEN protein levels.[18]

Regarding Ms. Newsome:

- Q. Ms. Newsome, endometrioid adenocarcinoma, diagnosed [at age] 53, and she had germline testing. She had a variant of -- a VUS in the MUTYH, correct?
  A. Yes.
  Q. And that was a monoallelic mutation, correct?
  A. Yes.
  Q. Is there any literature that associates a monoallelic MUTYH gene mutation, the VUS, with ovarian cancer?
  A. So mostly what I've seen is with regard to biallelic mutations, but some studies or I would say one key study that I do cite earlier in my report talks about monoallelic mutations and them having what we call a second hit in the tumor as contributing to ovarian cancer specifically. This plaintiff, I don't believe, had tumor testing but there is plausibility that an individual with a monoallelic mutation could develop ovarian cancer.
  Q. From a second hit --
  A. Possibly.[19]

- Although the clinical significance of this variant is unclear, and the genetic testing report indicates "there are currently insufficient data to determine if these variants cause increased cancer risk," MUTYH mutations have been observed in the germline of women with OvCa. Noteworthy is that MUTYH mutations have been reported in individuals with renal cell cancer . . . . Taken together, the possibility remains that there is a familial or inherited susceptibility to the cancers observed in Ms. Newsome and her family members.[20]

These representative opinions rest on multiple layers of speculation. First, additional genes need to be identified as contributing to ovarian cancer. Second, the

[18] Permuth Report at 147, Exhibit 1.
[19] Permuth Dep. at 335:2-22, Exhibit 2.
[20] Permuth Report at 147, Exhibit 1.

specific subtype of ovarian cancer associated with the mutation needs to be identified.[21] Third, Plaintiffs then would have to possess those mutations and the relevant cancer subtype. Suggesting to the jury that this speculative chain of events could happen and thus, is the cause of Plaintiffs' cancers, is improper and conjecture.

Expert opinions must be based on facts and not "speculation or conjecture." *Fedorczyk v. Caribbean Cruise Lines*, 82 F.3d 69, 75 (3d Cir. 1996). "*Daubert* holds that an inquiry into the reliability of scientific evidence under Rule 702 requires a determination as to its scientific validity." *In re Paoli R.R. Yard Pcb Litig.*, 35 F.3d 717, 742 (3d Cir. 1994); *see also In re J&J Talcum Powder Prods. Mktg., Sales Practices & Profs. Litig.*, 509 F. supp. 3d 116, 131 (D.N.J. 2020). Thus, an expert opinion "claiming a causal link" must be excluded if it is not based on existing scientific data. *Hoefling v. U.S. Smokeless Tobacco Co., LLC*, 576 F. Supp. 3d 262, 275 (E.D. Pa. 2021).[22]

That this area of science is evolving does not make Dr. Permuth's opinions admissible. Even in matters of "evolving" science, the court must exclude expert opinions that are "too speculative." *Henricksen v. Conoco Phillips Co.*, 605 F. Supp. 2d 1142, 1169 (E.D. Wash. 2009); *In re Bausch & Lomb Contacts Lens Solution*

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[21] *See* Dr. Kevin Holcomb's Expert Report at 6 ("It should be noted that even the hereditary syndromes are associated with distinct histologic types of EOC."), attached hereto as **Exhibit 4**.

[22] *Gen. Elec., Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.").

Prods. Liab. Litig., 693 F. Supp. 2d 515, 520 (D.S.C. 2010) ("speculation about future links between MoistureLoc and non-Fusarium infections is not sufficient"). The Federal Judicial Center explains: "Scientists may delay their decision while they or others gather more data. Judges, on the other hand, must rule on causation based on existing information…[A] judge does not have the option of suspending judgment until more information is available, but must decide after considering the best available science." Federal Judicial Center, *Reference Manual on Scientific Evidence* (3d ed. 2011), at Preface xiv, attached hereto as **Exhibit 5**.

The science and testing to date demonstrate that Plaintiffs have no known genetic mutations that are associated with ovarian cancer. That is all Dr. Permuth should be permitted to opine on with regard to genetics. Anything more is speculation and lacks reliability.

In an effort to concoct support for their unfounded positions, Dr. Permuth points to VUSs, suggesting that the VUSs may be yet-to-be-identified genetic mutations that caused Plaintiffs' cancers. The National Cancer Institute defines a VUS as "[a] change in a gene's DNA sequence that has an unknown significance on a person's health."[23] It is not known whether a VUS has any effect on cancer, let alone the type of ovarian cancer Plaintiffs each have. In addition, VUSs are rarely

[23] National Cancer Institution, NCI Dictionaries (available at https://www.cancer.gov/publications/dictionaries/cancer-terms/def/variant-of-uncertain-significance).

reclassified as deleterious.[24] In fact, Defendants' expert witness Dr. Michael Finan admits that some VUSs have been found to be "insignificant" and even protective against cancer.[25] As noted above, Dr. Permuth agrees there is no current association between the variants Plaintiffs have and ovarian cancer. Suggesting to the jury that genetic variants that have not been associated with ovarian cancer could be the cause of Plaintiffs' cancers is speculative and improper.

Additionally, these opinions mislead and prejudice the jury into believing association of Plaintiffs' ovarian cancers to an inherited genetic mutation is inevitable.[26] J&J's expert witnesses admit that most ovarian cancers are not associated with a genetic mutation. Dr. Kevin Holcomb testified that only 15-20% of ovarian cancers are believed to be associated with an inherited genetic mutation.[27] Moreover, he concedes that the majority of these cases are associated with mutations of the BRCA1 and 2 genes and Lynch syndrome, with up to 70% related to BRCA1

[24] Mighton et al. Variant classification changes over time in BRCA1 and BRCA2. Genetics in Medicine (2019) 21:2248–2254 ("Between 2012 and 2017, our laboratory has seen a clinically significant reclassification in a small number of cases. In this time period, only 0.3% (4/1209) of variants moved from inconclusive (likely pathogenic, VUS, and likely benign) to positive (pathogenic), and 0.08% (1/1209) moved from positive to inconclusive."), attached hereto as **Exhibit 6**.

[25] *Carl* Dep. of Dr. Michael Finan (June 26, 2024), at 112:5-10, attached hereto as **Exhibit 7**.

[26] Inherited genetic mutations on which Dr. Permuth opines are something a person is born with. This is different than somatic or "acquired" mutations, which occur after birth, and result from events or exposures that cause the gene mutation. *See* 2nd Amended Rule 26 Expert Report of Shawn Levy, PhD at 5, attached hereto as **Exhibit 8**.

[27] Dr. Kevin Holcomb 2024 Dep. at 344:15-17 ("15-20% of ovarian cancers are thought to be due to genetic predisposition syndromes now"), attached hereto as **Exhibit 9**.

and 2.[28] As noted above, it is undisputed that Plaintiffs do not have these genetic mutations.

Importantly, not everyone with an inherited genetic mutation gets cancer. Dr. Permuth agreed, "not all women with BRCA1 and 2 mutations develop ovarian cancer, so there's not what we call 100 percent penetrance."[29] Thus, the majority of ovarian cancer diagnoses have no association with inherited genetic mutations, and those that do are related to pathogenic mutations that Plaintiffs do not have. To suggest to the jury that an inherited genetic mutation is likely to be identified in the future as the cause of Plaintiffs' cancers is misleading, speculative, and not based on the scientific data.

Accordingly, the Court should exclude the speculative opinions of Dr. Permuth that suggest Plaintiffs' cancers are the result of imaginary, yet-to-be-identified genetic mutations.

V. DR. PERMUTH'S OPINIONS ON BIOLOGICAL PLAUSIBILITY ARE BASED ON FLAWED METHODOLOGY

A. Dr. Permuth Fails to Provide Opinions on Talcum Powder

Plaintiffs contend that J&J's talcum powder contains asbestos. In October 2019, the FDA found asbestos in a sample of J&J's Baby Powder, resulting in J&J

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[28] *See* Holcomb 2024 Dep. at 344:24-345:3, 345:16-20; s*ee also* Dr. Daniel Clarke-Pearson 2024 Report at 6 (evidence that up to 75% of hereditary ovarian cancers associated with BRCA1 and BRCA2 mutations), attached hereto as **Exhibit 10**; Dr. Judith Wolf 2024 Report at 3 (same), Exhibit 3.

[29] Permuth Dep. at 290:4-6, Exhibit 2.

recalling 33,000 bottles of the product.[30] Plaintiffs experts also testify to the presence of asbestos in Johnson's Baby Powder and its relationship to ovarian cancer.[31] Dr. Permuth chooses to ignore the presence of asbestos when opining on biological plausibility, focusing only on mechanistic studies concerning talc rather than studies that demonstrate that talc with asbestos is known to be genotoxic.[32]

As the Court previously recognized, biological plausibility asks "'whether the hypothesized causal link is credible in light of what is known from science and medicine about the human body and the potentially offending agent.'" *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Practices & Prods. Litig.*, 509 F. Supp. 3d 116, 174 (D.N.J. 2020) (quoting *Milward v. Acuity Specialty Prods. Grp., Inc.*, 639 F.3d 11, 25 (1st Cir. 2011)). Dr. Permuth ignores the "offending agent," which is talcum powder – a substance consisting of talc (both platy and fibrous), asbestos, and other constituents. She opines that it is not biologically plausible for talcum powder to contribute to ovarian cancer because talc does not migrate from the perineum to the ovaries, and talc does not cause malignant transformation. [33]

Although Dr. Permuth admits that asbestos is both a carcinogen and toxic, she

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30 Dyer, Owen. Johnson & Johnson Recalls its Baby Powder after FDA Finds Asbestos in Sample. BMJ (2019), attached hereto as **Exhibit 11**.

31 *See* Longo & Rigler 2nd Supp. Report (February 1, 2019) attached hereto as **Exhibit 12**; Longo 4th Supp. Report (November 17, 2023); *see also* Wolf 2024 Report at 12, Exhibit 3.

32 *See* International Agency for Research on Cancer (IARC), Volume 100C, *Arsenic, Metals, Fibres and Dusts*, at 288-291 (2012), attached hereto as **Exhibit 13**.

33 Permuth Report at 108, 121, Exhibit 1.

conducted no research to investigate the issue of whether asbestos causes mutations or otherwise focus on the mechanism by which asbestos causes cancer.[34] She ignored and failed to consider "the various constituents of the different types of talc or the different types of asbestos."[35] Her opinions are based on her beliefs of the product as a whole, without regard to its constituents.[36]

Dr. Permuth ignores the presence of asbestos because it "is one of the most potent carcinogens known," with all forms being carcinogenic.[37] IARC concluded that asbestos and talc containing asbestiform fibers cause ovarian cancer and "consumer products (e.g., cosmetics, pharmaceuticals) are the primary source of exposure to talc for the general population. Inhalation and dermal contact (i.e., through perineal application of talcum powders) are the primary routes of exposure."[38]

By ignoring asbestos and focusing solely on talc, one component of talcum powder, Dr. Permuth is engaging in impermissible cherry-picking. The cherry-picking of data and facts "does not reflect scientific knowledge, is not derived by

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34 Permuth Dep. at 198:7-10, Exhibit 2.

35 Permuth Dep. at 200:1-4, Exhibit 2.

36 Permuth Dep. at 42:14-43:1, Exhibit 2.

37 Wolf 2024 Report at 12, Exhibit 3; Clarke-Pearson 2024 Report at 8, Exhibit 10.

38 IARC 2012 at 232, Exhibit 13. It is noteworthy that IARC recently classified talc, even without asbestos, as "probably carcinogenic to humans (Group 2A) based on a combination of "limited" evidence for cancer in humans, "sufficient" evidence for cancer in experimental animals, and "strong" mechanistic evidence in human primary cells and experimental systems." Stayner L et al., IARC Working Group, The Carcinogenicity of talc and acrylonitrile, *The Lancet Oncology*, July 5, 2024.

scientific method and is not 'good science.'"[39] "[A]ny theory that fails to explain information that otherwise would tend to cast doubt on that theory is inherently suspect," and "courts have excluded expert testimony" where the expert selectively chose his support from the scientific landscape"[40] as Dr. Permuth has chosen to do here with regard to biological plausibility. It "is hardly scientific."[41] It is "inherently unreliable."[42]

The method used by Dr. Permuth to arrive at opinions on biological plausibility is flawed and scientifically unreliable. She did not conduct a comprehensive and scientific review of the literature concerning asbestos and thus, ignored and failed to consider scientific studies concerning the offending agent, which do not support her opinion. The Third Circuit has deemed expert opinions

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39 *In re Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation*, 524 F. Supp. 2d at 1176; *In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.*, 858 F.3d 787, 796–800 (3d Cir. 2017) ("An expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead 'selectively chooses his support from the scientific landscape.'"); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658, 676 (S.D.W. Va. 2014) "[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable.") *Pooshs v. Phillip Morris USA, Inc.*, 287 F.R.D. 543, 546 (N.D. Cal. 2012) ("A methodology may not be reliable if an expert fails to address and exclude alternative explanations for the data on which he bases his findings or rejects studies reporting contrary empirical findings."); *Abarca v. Franklin Cty. Water Dist.*, 761 F. Supp. 2d 1007, 1066 n.60 (E.D. Cal. 2011) ("A scientist might well pick data from many different sources to serve as circumstantial evidence for a particular hypothesis, but a reliable expert would not ignore contrary data, misstate the findings of others, make sweeping statements without support, and cite papers that do not provide the support asserted." (internal citations omitted)).

40 *In re Rezulin Prod. Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005).

41 *Lust By & Through Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 596 (9th Cir. 1996).

42 *In re Bausch & Lomb, Inc. Contact Lens Solution Prods. Liab. Litig.,* 2009 WL 2760462, at *14 (D.S.C. Aug. 26, 2009).

unreliable in situations like this, where the experts ignored facts when formulating their opinions.[43] Dr. Permuth's opinions on biological plausibility should be excluded.

B. Dr. Permuth Applied the Wrong Standard to Biological Plausibility

Dr. Permuth applied the wrong standard to biological plausibility. She stated, "[w]ith regard to the mechanism by which inanimate talc particles can migrate from the perineal area to the ovaries . . . Well - I can't find anything that proves -- I can't find anything that proves that hypothesis, if that's what you're asking. There is nothing out there."[44]

To be clear, Plaintiffs are not required to point to a precise study to prove with certainty biological plausibility. The *Reference Manual on Scientific Evidence* describes biological plausibility as a judgment based on existing knowledge as to whether an agent plausibly could cause an adverse outcome. Michael D. Green, *et al., Reference Manual on Scientific Evidence*, at 604-05 (3d Ed. 2011). Biologic plausibility lends credence to an inference of causation. *Id*.

Plaintiffs do not have the burden to prove the precise mechanism by which

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[43] *See Elcock v. Kmart Corp.,* 233 F.3d 734, 756 (3d 2000); *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 602 (D.N.J. 2002), *aff'd*, 68 F. App'x 356 (3d Cir. 2003) ("in order for an expert's opinions based on evidence to be reliable and admissible, "all of the relevant evidence must be gathered, and the assessment or weighing of that evidence must not be arbitrary, but must itself be based on methods of science.")

[44] Permuth Dep. at 176:16-177:7, Exhibit 2.

migration and ovarian carcinogenesis occur.[45] To require that a mechanism be proven is incorrect.[46] Dr. Permuth's contrary opinions regarding biological plausibility based on an improper standard of proof should be excluded.

The heightened standard that Dr. Permuth applies is not compatible with the civil law preponderance of evidence standard or with the definition of general

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[45] *See In re Fosamax Prod. Liab. Litig.*, 645 F. Supp. 2d 164, 181 (S.D.N.Y. 2009) ("[b]iologic plausibility is a judgment about whether an agent plausibly could cause a disease, based on existing knowledge about human biology and disease pathology" ... "That the mechanism remains unknown does not mean that the one proposed by the PSC's experts is not widely accepted as plausible."); *see also In re Neurontin Mktg., Sales Practices, & Prod. Liab. Litig.*, 612 F. Supp. 2d 116, 149 (D. Mass. 2009) (causation was supported by biologic plausibility notwithstanding the "robust debate in the scientific community" regarding the proposed mechanism); *In re Phenylpropanolamine (PPA) Prod. Liab. Litig.*, 289 F. Supp. 2d 1230, 1247 (W.D. Wash. 2003) ("The fact that the mechanism remains unclear does not call the reliability of the opinion into question."); *In re Avandia Mktg., Sales Practices & Products Liab. Litig*., 2007-MD-1871, 2011 WL 13576, at *4 (E.D. Pa. Jan. 4, 2011); *Rowland v. Novartis Pharm. Corp.*, 149 F.Supp.3d 553, *17 (2014) (defining biological plausibility as a reasonable association between exposure and disease based on what is known about the disease); *In re Fosamax Prods. Liab. Litig*., 2013 WL 155869, *3 (D.N.J. April 10, 2013) (defining biological plausibility as "coherence with existing knowledge"); *Bartoli v. Novartis Pharm. Corp.*, No. CIV.A. 3:13-0724, 2014 WL 1515870, at *7 (M.D. Pa. Apr. 17, 2014) (citing *In re Pfizer Inc. Sec. Litig.*, No. 04CIV.9866(LTS)(JLC), 2010 WL 1047618, at *6 (S.D.N.Y. Mar. 22, 2010) (allowing testimony regarding biological plausibility "[w]here a 'hypothesis has been deemed plausible and credible in the relevant medical literature' and where it is within an expert's field of expertise based on training, experience, and history of publication.'"); *Wicker v. Consol. Rail Corp.*, 371 F. Supp. 2d 702 (W.D. Pa. 2005) (defining biological plausibility as "coherence with existing knowledge"); *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 593 (D.N.J. 2002) (defining biological plausibility as the existence of a biologically plausible mechanism that could cause the adverse outcome of interest); *In re Trasylol Prod. Liab. Litig.*, No. 08-MD-01928, 2010 WL 1489730, at *7–*8 (S.D. Fla. Mar. 19, 2010) (plausible biological mechanism need not be "proven" just "reliable," and using terms of "can" and "may" in regard to such does not render opinion unreliable); *In re Chantix (Varenicline) Prod. Liab. Litig.*, 889 F. Supp. 2d 1272, 1300 (N.D. Ala. 2012) (mechanism theory deemed reliable despite "debate in the scientific community as to whether Dr. Bechara's dopamine depletion theory for Chantix can explain major depression and other neuropsychiatric injuries. . . .debate is not a basis for exclusion"); *In re Hanford Nuclear Reservation Litig.*, No. CY-91-3015-AAM, 1998 WL 775340, at *7 (E.D. Wash. Aug. 21, 1998) (" 'biological plausibility' is not the same as 'biological certainty.'. . . [s]uch certainty cannot be attained.").

[46] *In re Trasylol Products Liability Litigation*, 2010 WL 1489730, at *7–*8.

causation. Longstanding legal jurisprudence govern the standard of proof in a civil case. In the Third Circuit and elsewhere, a plaintiff must prove the elements of the claims by a preponderance of evidence. This holds true for evidence of causation, including expert testimony. Plaintiffs are required to prove causation is "more probable than not."[47] "It would be unreasonable to conclude that the subject of scientific testimony must be 'known' to a certainty; arguably, there are no certainties in science."[48]

As the U.S. Supreme Court has recognized, outside the courtroom, it is a fallacy that scientists insist on certainty or near certainty in making judgments. "[M]edical professionals and researchers do not limit the data they consider to the results of randomized clinical trials or to statistically significant evidence."[49] The Third Circuit is clear that "it would be unreasonable to conclude that the subject of scientific testimony must be 'known' to a 'certainty.'"[50]

Nor will such testimony "assist the trier of fact." To the contrary, it will tend to obfuscate and confuse. Opinions that are based on the incorrect legal standard cannot be helpful to the jury and, in fact, create confusion. The very purpose of

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47 *In re Paoli R.R. Yard PCB Litig*., 35 F.3d 717, 780 (3d Cir. 1994).

48 *Daubert,* 509 U.S. at 590. *See also Horan v. Dilbet, Inc*., 2015 WL 5054856, *13 (D.N.J. Aug. 26, 2015) (noting the unreasonableness of subjecting scientific testimony to a certainty standard).

49 *Matrixx Initiatives, Inc. v. Siracusano,* 563 U.S. 27, 40-42 (2011)

50 *Horan v. Dilbet*, *Inc.,* 2015 WL 5054856, *13 (D.N.J. Aug. 26, 2015) (*citing Daubert*, 509 U.S. at 590).

expert testimony is to aid the jury and help them understand the evidence or determine a fact in issue.[51] In its gate-keeper role, the court is tasked with balancing the admission of reliable, helpful expert testimony with the exclusion of that which is misleading or confusing.[52]

Expert witness testimony couched in the phrases like "I can't find anything that proves that hypothesis" is powerful and resonant.[53] And when uttered from the mouths of experts, this testimony poses a strong risk of misleading the jury to give it undue weight.[54]

The "certainty" testimony is sure to confuse the jury during deliberation because it contradicts the jury instruction that plaintiffs must prove their claims by a preponderance of the evidence. *See Smith v. Ryan,* 813 F.3d 1175, 1199 (9th Cir. 2016) ("If a trained psychiatrist has difficulty with the categorical 'beyond a reasonable doubt' standard, the untrained lay juror—or indeed even a trained judge—who is required to rely upon expert opinion could be forced by the criminal law standard of proof to reject commitment for many patients desperately in need of institutionalized psychiatric care."). Dr. Permuth's opinions are unreliable and

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51 Fed. Rule Evid. 702 (a).

52 *See Daubert*, 509 U.S. at 595*; In re Paoli R.R. Yard PCB Litig*., 35 F.3d 717, 746 (3d Cir. 1994) ("[A]dmissibility of scientific testimony turns not only on reliability but also the possibility that admitting the evidence would overwhelm, confuse, or mislead the jury…in conducting this balancing inquiry, there is a presumption of helpfulness.").

53 Permuth Dep. at 177:5-7, Exhibit 2.

54 *See Nye v. Mistick,* 2015 WL 11511580, *5, n.3 (M.D. Pa. Feb. 24, 2015) (cautioning that experts that exude improper authority can lead juries to give their opinions more weight).

amount to nothing more than a personal, subjective standard for weighing evidence and should not be permitted.

Dr. Permuth cannot provide coherent opinions on biological mechanism based on an incorrect standard. Her opinions should be excluded.

VI. CONCLUSION

For this and the other foregoing reasons, the Court should grant the PSC's motion to exclude the opinions of Dr. Permuth from this proceeding concerning (1) potential genetic mutations as the cause of Plaintiffs' cancer and (2) biological plausibility.

Respectfully submitted,

/s/ *Michelle A. Parfitt*
Michelle A. Parfitt
ASHCRAFT & GEREL, LLP
1825 K Street, NW, Suite 700
Washington, DC 20006
Tel: 202-783-6400
Fax: 202-416-6392
mparfitt@ashcraftlaw.com

/s/ *P. Leigh O'Dell*
P. Leigh O'Dell
BEASLEY, ALLEN, CROW, METHVIN, PORTIS & MILES, P.C.
218 Commerce Street
Montgomery, AL 36104
Tel: 334-269-2343
Fax: 334-954-7555
Leigh.odell@beasleyallen.com
Plaintiffs' Co-Lead Counsel

/s/ *Christopher M. Placitella*
Christopher M. Placitella
COHEN, PLACITELLA & ROTH, P.C.
127 Maple Avenue
Red Bank, NJ 07701
Tel: 732-747-9003
Fax: 732-747-9004
cplacitella@cprlaw.com
Plaintiffs' Liaison Counsel

PLAINTIFFS' EXECUTIVE COMMITTEE:

Warren T. Burns
BURNS CHAREST LLP
500 North Akard Street, Suite 2810
Dallas, TX 75201
Tel: 469-904-4551
Fax: 469-444-5002
wburns@burnscharest.com

Richard Golomb
GOLOMB & HONIK, P.C.
1515 Market Street, Suite 1100
Philadelphia, PA 19102
Tel: 215-985-9177
rgolomb@golombhonik.com

Hunter J. Shkolnik
NAPOLI SHKOLNIK PLLC
360 Lexington Avenue, 11thFloor
New York, NY 10017
Tel: 212-397-1000
hunter@napolilaw.com

PLAINTIFFS' STEERING COMMITTEE:

Laurence S. Berman
LEVIN, SEDRAN & BERMAN LLP
510 Walnut Street, Suite 500
Philadelphia, PA 19106
Tel: 215-592-1500
Fax: 215-592-4663
lberman@lfsblaw.com

Timothy G. Blood
BLOOD, HURST & O'REARDON, LLP
701 B Street, Suite 1700
San Diego, CA 92101
Tel: 619-338-1100
Fax: 619-338-1101
tblood@bholaw.com

Sindhu S. Daniel
BARON & BUDD, P.C.

Jeff S. Gibson
WAGNER REESE, LLP

3102 Oak Lawn Avenue, #1100
Dallas, TX 75219
Tel: 214-521-3605
Fax: 214-520-1181
sdaniel@baronbudd.com

Kristie M. Hightower
LUNDY, LUNDY, SOILEAU & SOUTH, LLP
501 Broad Street
Lake Charles, LA 70601
Tel: 337-439-0707
Fax: 337-439-1029
khightower@lundylawllp.com

Victoria Maniatis
SANDERS PHILLIPS GROSSMAN, LLC
100 Garden City Plaza, Suite 500
Garden City, NJ 11530
Tel: 516-640-3913
Fax: 516-741-0128
vmaniatis@thesandersfirm.com

Christopher V. Tisi
LEVIN PAPANTONIO
316 South Baylen St.
Pensacola, FL 32502
(850) 435-7000
ctisi@levinlaw.com

11939 N. Meridian St.
Carmel, IN 46032
Tel: (317) 569-0000
Fax: (317) 569-8088
jgibson@wagnerreese.com

Daniel R. Lapinski
MOTLEY RICE LLC
210 Lake Drive East, Suite 101
Cherry Hill, NJ 08002
Tel: 856-667-0500
Fax: 856-667-5133
dlapinski@motleyrice.com

Carmen S. Scott
MOTLEY RICE LLC
28 Bridgeside Boulevard
Mount Pleasant, SC 29464
Tel: 843-216-9162
Fax: 843-216-9450
cscott@motleyrice.com